



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

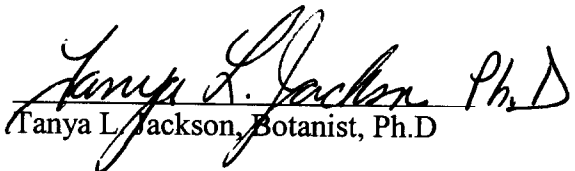
Memorandum

APR 26 2004

Date:
From: Interdisciplinary Scientist, Division of Dietary Supplements Program, Office of
Nutritional Products, Labeling and Dietary Supplements, HFS-821
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

Subject of the Notification: Conseco Brand Sea Buckthorn Fruit Oil
(resubmission)
Firm: Conseco Sea Buckthorn Co., Ltd.
Date Received by FDA: January 23, 2004
90-Day Date: April 24, 2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and
Cosmetic Act, the attached 75-day premarket notification and related correspondence for the
aforementioned substance should be placed on public display in docket number 95S-0316 as
soon possible since it is past the 90-day date. Thank you for your assistance.


Tanya L. Jackson, Botanist, Ph.D.

95S-0316

RPT 230



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

APR - 6 2004

Han Xu, M.D.
Senior Researcher
Conseco Sea Buckthorn Co., Ltd
Jia 1 Fuxing Road, Haidian District
Beijing 100038
P.R. China

Dear Dr. Xu:

This is to inform you that the notification that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on January 23, 2004. Your notification concerns the substance "Conseco Brand Sea Buckthorn Fruit Oil", extracted from *Hippophae rhamnoides* L., that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell 100 ml bottle of your new ingredient "Conseco Brand Sea Buckthorn Fruit Oil". You recommend taking 5 ml-10 ml twice daily for a total daily intake of 20 ml per day.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "Conseco Brand Sea Buckthorn Fruit Oil" will reasonably be expected to be safe.

The notification did not clearly describe the composition of "Conseco Brand Sea Buckthorn Fruit Oil." For example, Conseco provides a list of the components of "Conseco Brand Sea Buckthorn Fruit Oil". This list accounts for less than 1% of the composition of "Conseco Brand Sea Buckthorn Fruit Oil" ($150\text{mg}+5\text{mg}+100\text{mg}+60\text{mg} = 315\text{mg} / 100\text{g} = 0.3\%$), that you intend to market.

Total carotenoids (mg / 100g)	≥ 150
β -carotene (mg / 100g)	≥ 5
Vitamin E (mg / 100g)	≥ 100
α -tocopherol (mg / 100g)	≥ 60


Moreover, your notification cited clinical supportive data on "Conseco Brand Sea Buckthorn Fruit Oil", however, no such data was included in your submission.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the "Conseco Brand Sea Buckthorn Fruit Oil" product, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of January 23, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,


for Susan J. Walker, M.D.
Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition